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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,872	02/07/2002	John C. Alexander	61765.00334	4170

22907 7590 06/06/2005

BANNER & WITCOFF  
1001 G STREET N W  
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WASHINGTON, DC 20001

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/914,872

**Applicant(s)**

ALEXANDER ET AL.

**Examiner**

San-ming Hui

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-10,12,13,16-18 and 21-44 is/are pending in the application.  
4a) Of the above claim(s) 24-29,31-33,35-40 and 42-44 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,2,6-10,12,13,16-18,21-23,30,34 and 41 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9-5-01.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of the specie, quinapril, in response filed March 3, 2005 is acknowledged. The traversal is on the ground(s) that the instant disclosed species are all ACE inhibitors. This is not found persuasive because although the instant disclosed species might belong to a common class of compounds, they are individually patentably distinct. These agents have different chemical structures and belong to different classifications. Therefore, the search for all the species encompassed by the claims would impose the undue burden to the Office.

The requirement is still deemed proper and is therefore made FINAL.

The cancellation of claims 3-5, 11, 14-15, 19-20 is acknowledged.

Claims 1,2,6-10,12,13,16-18 and 21-44 are pending.

Claims 24-29, 31-33, 35-40, and 42-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 3, 2005.

Claims 1, 2, 6-10, 12, 13, 16-18, 21-23, 30, 34, and 41 are examined to the extent they read on the elected specie.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-10, 12, 13, 16-18, 21-23, 30, 34, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO96/40257 ('257) from IDS filed September 5, 2001, Jandeau et al. (Am. J. Cardiol., 1996;79:635-638), and Dahlstrom et al. (Am J Cardiol. 1993 Jan 21;71(3):29A-33A).

'257 teaches eplerenone as useful in treating congestive heart failure. '257 also teaches that a combination of other compounds that is a same class as eplerenone, diuretics and ACE inhibitors captopril as useful in treating heart failure (See page 9, lines 21-24, also page 6, lines 25 – page 7, line 6).

Jandeau et al. teaches quinapril as effective in treating congestive heart failure (See the abstract, page 637, col. 2 – page 638, col. 2).

Dahlstrom et al. teaches furosemide, and/or spironolactone, and/or digoxin combined with ACE inhibitor captopril as effective in treating congestive heart failure (See the abstract and page 32A-33A, discussion Section).

The references do not expressly teach the combination of the herein claimed agents in a single composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the herein claimed agents into a single composition.

One of ordinary skill in the art would have been motivated to combine the herein claimed agents into a single composition. The herein claimed agents are known to be useful in treating congestive heart failure, both individually or in combination, therefore,


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combining these agents into a single composition useful for the very same purpose, i.e., treating congestive heart failure, would be prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
San-ming Hui  
Primary Examiner  
Art Unit 1617